

**REMARKS**

Claims 16, 18, and 21 are canceled. Amended claims 13-15, 17, 19-20, and 22-25 and new claims 26 – 31 are presented for continued examination. Claims 13 - 40 are fully supported by the originally-filed specification. For example, paragraphs 10, 73 - 74, 88, Example 6 (paragraphs 170 - 189), and 186 - 189 of the printed publication demonstrate support for amended claims 13 - 25. Paragraphs 73 -74, 88, Example 6 (paragraphs 170 - 189), 186 - 189 and 210 - 13 of the printed publication demonstrate support for new claims 26 - 31.

**Objection – Informalities**

Currently pending claims 14-15, 23 and 25 stand objected to. The Examiner has requested that “the abbreviations “5-FU”; “5-FUDR”; “IL-2”; and “IL-12” should be preceded in their first occurrence by the specific identity of the entities said abbreviations are intended to represent in the claims.” (10/2/06 Office Action at page 2). As to “5-FU”, applicants respectfully note that this term has been defined as “fluoropyrimidines” at paragraph 40 of the printed publication. As to “5-FUDR”, applicants respectfully note that this term has been defined as “5-fluorodeoxyuridine” at paragraph 59 of the printed publication. As to “IL-2” and “IL-12”, applicants respectfully note that each of these terms (interleukin-2 and interleukin-12, respectively) have been discussed as “well known to those skilled in the art and a list of such can be found in any modern biology/medicine text” at paragraph 210 of the printed publication. The appropriate corrections to Claims 14-15, 23 and 25 have been made. Withdrawal of this grounds for objection is respectfully requested.

**Objection – Double Patenting**

Currently pending claims 13-15, 17, 19-20, and 22 stand rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over certain claims of U.S. Patents Nos. 6,645,946; 7,012,068; and 6,982,255. Pursuant to 37 CFR 1.321(c), Applicants agree to file a terminal disclaimer in order to disclaim any term of the patent issuing from this application past the expiration of U.S. Patents Nos. 6,645,946; 7,012,068; and 6,982,255, and will file terminal disclaimers herewith.

**Rejection under 35 U.S.C. 112(1)—Undue Experimentation**

Currently pending claims 13-15, 17, 19-20 and 22-25 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use an invention commensurate in scope with the claims. The Examiner states that “Claim 13-25 are rejected under 35 U.S.C., first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim with respect to treating any cancer in a subject broadly in claims 13 - 17 and 19 -25, and/or those numerous cancers listed in claim 18.” (10/2/07 Office Action, pp. 7-8). The Examiner further states that “the specification fails to provide sufficient support of the broad use of the said admixture for treating numerous and varied cancers recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of chemotherapeutic agents in the presence of galactomannan and cancers encompassed by the

instant claims suitable to practice the claimed invention.” (*Id.*, pp. 10-11). Applicants respectfully disagree.

In response, Applicants have amended independent claim 13 so as to specify that the claimed invention recites a method for “improving biodistribution of a chemotherapeutic agent in the body.” Support for this amendment is found, for example, at paragraphs 73 - 74 of the application as filed and at Example 6 (paragraphs 170 - 189) of the application as filed. For example, “improved biodistribution” means increased exposure of tissue (for example, liver, kidney, tumor and plasma) to a chemotherapeutic agent. Such improved biodistribution can be measured, for example, by the methods described in Example 6 of the specification as filed.

Applicants respectfully submit that, although Applicants disagree with the Examiner, the amended claims directed to “improving biodistribution of a chemotherapeutic agent in the body” render this rejection moot. Withdrawal of this grounds for rejection is respectfully requested.

#### **Rejection under 35 U.S.C. 112(2)—Indefiniteness**

Currently pending claims 19-20 and 22-25 stand rejected under 35 U.S.C. 112(2) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner has rejected claims 13-25 as indefinite, stating that “In all occurrences of the presented claims, in the absence of the specific ratio between galactomannan and other agents, render the claims indefinite wherein applicant fails to articulate the specific ratio, requisite to identifying the admixture having galactomannan and other agents.”)(10/2/06 Office Action at pp. 11- 12). Applicants disagree.

Paragraph 10 of the specification as filed provides a specific range of suitable ratios for reducing toxicity, as shown below:

In one aspect, the mixture in the formulation contains an amount of one or more polysaccharides and one or more chemotherapeutic agents in a ratio suitable for reducing any toxic side-effect in the subject. The polysaccharide to chemotherapy ratio could be in the range from 10:1 up to 1:10. With the 50,000 MW modified galactomannan the optimum ratio was in the range from 6:1 to 1:3. In another aspect, the mixture contains an amount of one or more polysaccharides and one or more chemotherapeutic agents in a ratio suitable for enhancing efficacy of chemotherapeutic effect for treating the cancer.

Applicants respectfully submit that, although Applicants disagree with the Examiner, the amended claims incorporate a specific range or ratios of galactomannan and other agents present in the admixture. The amendment thus renders this rejection moot. Withdrawal of this grounds for rejection is respectfully requested.

**CONCLUSION**

Claims 13-15, 17, 19-20 and 22-25 as amended herewith and new claims 26-30 are presented for continued examination. Early and favorable consideration on the merits is earnestly solicited. If any additional fee is due, the amount of such fee may be charged to Deposit Account No. 50-1561.

Respectfully submitted,  
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